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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Pharmacy Survey on Patient Safety Culture Comparative Database." In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by [insert date 60 days after date of publication].

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@ahrq.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Pharmacy Survey on Patient Safety Culture Comparative Database.

In 1999, the Institute of Medicine called for health care organizations to develop a "culture of safety" such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; *To Err is Human: Building a Safer Health System*). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Pharmacy Survey on Patient Safety Culture with OMB approval (OMB NO. 0935-0183; Approved 08/12/2011). The survey is designed to enable pharmacies to assess staff opinions about patient and medication safety and quality-assurance issues, and includes 36 items that measure 11 dimensions of patient safety culture. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in October 2012 on the AHRQ Web site.

The AHRQ Pharmacy Survey on Patient Safety Culture (Pharmacy SOPS) Comparative Database consists of data from the AHRQ Pharmacy Survey on Patient Safety Culture. Pharmacies in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Pharmacy SOPS Database is modeled after three other SOPS databases: Hospital SOPS [OMB NO. 0935-0162; Approved 05/04/2010]; Medical Office SOPS [OMB NO. 0935-0196; Approved 06/12/12]; and Nursing Home SOPS [OMB NO. 0935-0195; Approved 06/12/12] that were originally developed by AHRQ in response to requests from hospitals,

medical offices, and nursing homes interested in knowing how their patient safety culture survey results compare to those of other similar health care organizations.

Rationale for the information collection. The Pharmacy SOPS survey and the Pharmacy SOPS Comparative Database will support AHRQ's goals of promoting improvements in the quality and safety of health care in pharmacy settings. The survey, toolkit materials, and comparative database results are all made publicly available on AHRQ's website. Technical assistance is provided by AHRQ through its contractor at no charge to pharmacies, to facilitate the use of these materials for pharmacy patient safety and quality improvement.

The goal of this project is to create the Pharmacy SOPS Comparative Database. This database will:

- 1) allow pharmacies to compare their patient safety culture survey results with those of other pharmacies,
- 2) provide data to pharmacies to facilitate internal assessment and learning in the patient safety improvement process, and
- 3) provide supplemental information to help pharmacies identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, WESTAT, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare

services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve these goals the following data collections will be implemented:

- 1) Registration Form -- The point-of-contact (POC), the pharmacy manager or a survey participating organization, completes a number of data submission steps and forms, beginning with completion of an online Registration Form. The purpose of this form is to collect basic demographic information about the pharmacy and initiate the registration process.
- 2) Pharmacy Background Characteristics Form -- The purpose of this form, completed by the pharmacy manager or a participating organization, is to collect background characteristics of the pharmacy. This information will be used to analyze data collected with the Pharmacy SOPS survey.
- 3) Data Use Agreement -- The purpose of the data use agreement, completed by the pharmacy manager or participating organization is to state how data submitted by pharmacies will be used and provide confidentiality assurances.
- 4) Data Files Submission -- POCs upload their data file(s), using the pharmacy data file specifications, to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted. The number of submissions to the database is likely to vary each year because pharmacies do not administer the survey and submit data every year.

Survey data from the AHRQ Pharmacy Survey on Patient Safety Culture are used to produce three types of products: 1) A Pharmacy SOPS Comparative Database Report that is made publicly available on the AHRQ Web site, 2) Individual Pharmacy Survey Feedback Reports that are confidential, customized reports produced for each pharmacy that submits data to the database (the number of reports produced is based on the number of pharmacies submitting each year); and 3) Research data sets of individual-level and pharmacy-level de-identified data to enable researchers to conduct analyses.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the database. An estimated 150 POCs, each representing an average of 10 individual pharmacies each, will complete the database submission steps and forms annually. Completing the registration form will take about 5 minutes. The Pharmacy Background Characteristics Form is completed by all POCs for each of their pharmacies (150 x 10 = 1,500 forms in total) and is estimated to take 5 minutes to complete. Each POC will complete a data use agreement which takes 3 minutes to complete and submitting the data will take an hour on average. The total burden is estimated to be 296 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$14,392 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
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Registration Form	150	1	5/60	13
Pharmacy Background				
Characteristics Form	150	10	5/60	125
Data Use Agreement	150	1	3/60	8
Data Files Submission	150	1	1	150
Total	600	NA	NA	296

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Registration Form	150	13	\$48.62	\$632
Pharmacy Background				
Characteristics Form	150	125	\$48.62	\$6,078
Data Use Agreement	150	8	\$48.62	\$389
Data Files Submission	150	150	\$48.62	\$7,293
Total	600	296	NA	\$14,392

*Mean hourly wage rate of \$48.62 for General and Operations Managers (SOC code 11-1021) was obtained from the May 2012 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 446110 – Pharmacies and Drug Stores located at http://www.bls.gov/oes/current/naics5_446110.htm.

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 22, 2013

Richard Kronick,
AHRQ Director

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